

IN RE PHARMACEUTICAL INDUSTRY	) MDL No.1456
AVERAGE WHOLESALE PRICE	)
LITIGATION	) Master File No. 01-CV-12257-PBS
	) Subcategory No. 06-CV-11337-PBS
	)
THIS DOCUMENT RELATES TO:	) Judge Patti B. Saris
<i>United States of America ex rel. Ven-A-Care of</i>	) Magistrate Judge Marianne B. Bowler
<i>the Florida Keys, Inc., et al. v. Boehringer</i>	)
<i>Ingelheim Corporation, et al.</i> , Civil Action No.	)
07-10248-PBS	)
	)

Defendants ask this Court to let BIC and BIPI off the hook for the false prices reported by Roxane. They apparently understand that in order to obtain such a ruling at summary judgment, they must convince the Court that there is “no evidence” to support liability under either of plaintiffs’ theories. *See, e.g.*, BIC/BIPI’s Reply Memorandum (“Reply Mem”), at 1, 2, 9-10. They cannot do so, however, in the face of abundant evidence that BIC and BIPI officials knowingly assisted with, and exercised authority over, Roxane’s sales and marketing efforts, including setting and raising false AWP’s for the Subject Drugs, and developing the overall policies for setting and raising reported prices. Since factual disputes (such as who approved the ipratropium bromide marketing plan) are not properly resolved at summary judgment, this sur-reply focuses on the legal issues bearing directly on defendants’ motion.

The threshold issues presented by this motion are whether defendants ignored corporate

distinctions by operating BIPI and Roxane as part of a single enterprise, and whether piercing Roxane's corporate veil would serve the interests of the public convenience, fairness and equity. As detailed in the United States' opposition, there is extensive evidence that Roxane and BIPI operated as part of a common business unit; that they shared management, employees, and customers; and that decisions at both companies were made to benefit their shared corporate parent (BIC), and the broader Boehringer Ingelheim group. Defendants' own employees described BIPI and Roxane as "intermingled," and expressed concern that customers could not recognize the corporate distinctions between the companies. *See* United States' Response to BIC/BIPI SOF, ¶ 12.

Defendants' claim that the United States is trying to "rewrite bedrock First Circuit law" on piercing the corporate veil, Reply Mem at 1, is simply wrong. The United States correctly pointed out that fraudulent intent is not a prerequisite to piercing the corporate veil. In *Brotherhood of Locomotive Eng'rs v. Springfield Terminal Ry. Co.*, the First Circuit observed that "Federal Courts are not bound by the strict standards of the common law alter ego doctrine which would apply in a tort or contract action," and unambiguously stated that there is "*no litmus test* in the federal courts governing when to disregard corporate form." On the contrary, "the rule in federal cases is founded *only* on the broad principle that a corporate entity may be disregarded *in the interests of public convenience, fairness and equity*. 210 F.3d 18, 25 (1st Cir. 2000) (internal citation and quotation omitted) (emphasis supplied). In light of this pronouncement, defendants' argument that a showing of fraudulent intent is required is not convincing. Defendants premise their argument on an earlier decision, *United Elec., Radio & Mach. Workers v. 163 Pleasant St. Corp.*, 960 F.2d 1080, 1091-93 (1<sup>st</sup> Cir 1992), in which the First Circuit held *only* that, in an ERISA case, "personal jurisdiction cannot be exercised over a foreign company

through a corporate veil-piercing theory absent a showing of fraud.” See *Mass. Carpenters Central Collection Agency v. Belmont Concrete Corp.*, 139 F.3d 304, 308 (1st Cir. 1998) (explaining that “[f]undamentally, *163 Pleasant St.* is a case about personal jurisdiction: whether there was personal jurisdiction in Massachusetts over a foreign parent corporation based on the activities of a Massachusetts subsidiary.”)<sup>1</sup>

While defendants correctly point out that the *163 Pleasant St.* factors have been cited in other decisions, they do not mention that none of those decisions hold that a showing of fraudulent intent is required to pierce the corporate veil. Instead, such decisions simply cite the *163 Pleasant St.* factors as relevant to the veil-piercing inquiry. For example, *InterGen N.V. v. Grina*, 344 F.3d 134 (1st Cir. 2005), addressed whether or not a parent corporation was bound by its subsidiary’s agreement to arbitrate because the parent and subsidiary were alter egos. In holding that the parent corporation was not so bound, the court referred to *163 Pleasant St.* as “suggest[ing]” a useful analytical framework, but the Court’s holding was expressly premised on the fact that “no compelling policy objective” was served by finding the companies to be alter egos, and the decision contains no substantive discussion of any fraudulent intent requirement. *Id.* at 148-50. Likewise, in *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 39-40 (D. Mass. 2000), the court referenced the *163 Pleasant St.* factors in dismissing a parent corporation, but the holding was based on the fact that the *only* allegation related to piercing the corporate veil was that the parent corporation was the sole shareholder of

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<sup>1</sup>Defendants’ attempt to distinguish *Mass. Carpenters* on the ground that its holding relates only to “labor law” is illogical. Both the *163 Pleasant St.* and *Mass. Carpenters* decisions involved ERISA claims. In any event, the relevant standard is laid down in the First Circuit’s subsequent decision in *Brotherhood of Locomotive Eng’rs*.

the subsidiary.<sup>2</sup>

In any event, even if the “fraudulent intent requirement” articulated in *163 Pleasant St.* were relevant at all outside of the ERISA context and to determine something other than personal jurisdiction, that would not preclude piercing the corporate veil here, where plaintiffs have made the very evidentiary showing recognized in *163 Pleasant St.*: “some cognizable showing that the parent corporation maintained the subsidiary to avoid its statutory responsibilities, looted the subsidiary, or so undercapitalized the subsidiary that the latter could not reasonably have been expected to meet its obligations.” *Id.* at 1091-93. Here, the evidence shows that BIC caused Roxane to pay it a \$320 million dividend in 2002, leaving Roxane – for the first time – with debts greatly exceeding its total equity. Such siphoning of assets satisfies a requirement to show fraudulent intent. *See, e.g., United States v. Bridle Path Enterprises, Inc.*, 2001 WL 1688911, \*3 (D. Mass. 2001); *c.f. Gambro Healthcare, Inc.*, 115 F.Supp.2d at 39-40 (dismissing complaint against parent corporation, but noting that there was not “any allegation suggest[ing] that [parent], dreading a future day of reckoning in this case, has stripped [its subsidiary] of assets.”)

Defendants struggle to supply a rationale for why Roxane paid the \$320 million when it did, but cannot escape the fact that the dividend was paid *after* defendants learned that litigation was likely, and constituted a dramatic departure from Roxane’s prior levels of capitalization. Moreover, at least one of defendants’ newly proffered explanations -- that Roxane paid the dividend because it realized \$175 million in proceeds from the sale of its palliative care products

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<sup>2</sup>*United States v. Mountzoures*, 376 F. Supp. 2d 13, 18-19 (2005) is similarly unhelpful: although citing *163 Pleasant St.* as providing “guidance” to the veil-piercing inquiry, the decision premised its holding on the “totality of the circumstances,” including the fact that the plaintiff, having executed a contract with the defendant subsidiary corporation, was not confused as to which defendants were bound by the contract.

-- is misleading. Although Roxane did sell its pain products for that sum, its total income for 2001 *including the sale proceeds* was \$139 million. *See* United States' Response to BIC/BIPI SOF, ¶ 36. Defendants do not counter the essential fact that the \$320 million dividend exceeded Roxane's total income from the preceding *five years*, and was in addition to \$41 million and \$50 million dividends paid to BIC in 1999 and 2000, respectively. *Id.*

**B. There is a Triable Issue as to Whether BIC And BIPI Are Directly Liable Under the False Claims Act**

In large part, defendants' reply memorandum attempts to explain away the United States' extensive evidence of direct liability by describing every instance of BIC and/or BIPI's involvement in Roxane's pricing and marketing as a "unique" circumstance and therefore, impliedly, an aberration. Such characterizations ring hollow in the face of evidence that BIC and BIPI employees took part in and approved decisions to set inflated AWP's -- conduct at the heart of this litigation. Defendants' attempt to minimize the importance of this evidence by claiming that such employees played only "supervisory" roles and "merely" approved prices originally proposed by Roxane personnel, misses the mark entirely. *Assisting* with (let alone authorizing) the submission of false prices by others creates liability under the False Claims Act (FCA). *See, e.g., United States ex rel. Riley v. St Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (False Claims Act "applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud").

Defendants' claim that the United States has not shown that BIC and BIPI were actively involved in the pricing of each and every drug at issue is also a red herring. Defendants cite no authority supporting their claim that BIC and BIPI's involvement in the underlying conduct must be proven "on a drug-by-drug basis," and no such authority exists. Prior holdings of this Court

require only that evidence of *falsity* be established drug by drug, and there is no requirement in the FCA that proof of a defendant's complicity in an overall fraudulent price reporting scheme must extend to every product included within the scheme. On the contrary, FCA liability extends so far as to include those operating a *policy* that causes others to submit false claims. *See, e.g., United States v. President and Fellows of Harvard College*, 323 F. Supp. 151, 186-87 (D. Mass. 2004). Here, BIC and BIPI employees helped to develop, and ultimately endorsed, Roxane's practice of reporting inflated AWP's, including specific decisions to set inflated AWP's for several of the Subject Drugs. This evidence, in conjunction with proof that the reported AWP's for each of the Subject Drugs were in fact false, is more than sufficient to create a triable issue as to BIC and BIPI's liability under the FCA.

Finally, defendants claim that the United States “repeatedly misleads this Court” by relying on a “draft” common pricing policy and procedure applicable to both BIPI and Roxane’s branded/branded generic products. (Reply Mem. at 14) It is the defendants who mislead. Although the document in question is labeled “draft,” undisputed evidence establishes that the pricing for Roxicodone (and other branded generic products) was approved in *exactly* the manner described in the pricing policy and procedure: first by a joint Roxane and BIPI pricing committee, and then by Mr. Berkle as head of the Business Unit, and Mr. Gerstenberg, as head of Boehringer Ingelheim Corporation. *See United States’ Response to BIC/BIPI SOF*, ¶¶ 51, 75.<sup>3</sup> Given the precise match between the procedure described in the policy, and the actual manner in which prices were approved, whether or when defendants formally enacted a “final” policy is irrelevant, since they adopted and followed the policy in practice. The label “draft” is thus a

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<sup>3</sup>This was confirmed by Roxane’s own expert. *See Exhibit A hereto (5/20/2009 Macey Dep., at 413:6 - 415:20)*

distinction without a difference.

## CONCLUSION

Defendants' spirited protests fall short; they misstate the appropriate legal standard and defendants' motion for summary judgment should be denied because the undisputed evidence supports plaintiffs' claims against them under a veil piercing theory and for direct liability under the False Claims Act.

Respectfully submitted,

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DATED: October 6, 2009

### **CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ James J. Fauci

James J. Fauci

Assistant U.S. Attorney

Dated: October 6, 2009



# Exhibit A

*United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.*

Civil Action No. 07-10248-PBS

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UNITED STATES OF AMERICA, ex rel,

VEN-A-CARE, FLORIDA KEYS, INC.,

Plaintiffs,

Case No. 07-10248

-against-

BOEHRINGER INGELHEIM CORPORATION,

et al.,

Defendants.

-----x

May 20, 2009

8:03 a.m.

CONFIDENTIAL

Continued deposition of JONATHAN R.

MACEY, taken at the offices of Kirkland & Ellis,  
Citigroup Center, 153 East 53rd Street, New York,  
New York, before Georgette K. Betts, a Certified  
Shorthand Reporter, Registered Professional  
Reporter and Notary Public within and for the  
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ROSLYN G. POLLACK, ESQ.  
(via phone)

1 redirect.

2 THE WITNESS: Okay.

3  
4 EXAMINATION

5 BY MR. FAUCI:

6 Q. Focusing on Exhibit 11, Macey Exhibit  
7 11, I believe you just testified that you saw no  
8 evidence that this pricing policy was ever put  
9 into place; is that correct?

10 A. Yes.

11 Q. I'll ask you to juggle between Exhibit  
12 11 and Exhibit 12 just for a moment.

13 A. All right. If I can find it.

14 Q. It's the Roxane --

15 A. I got it.

16 Q. In Exhibit 11, it lists the pricing  
17 approvals as first the PTC Committee.

18 Do you see that?

19 A. Yes.

20 Q. Then executive vice president Ethical  
21 Pharmaceuticals is second?

22 A. Yes.

1 Q. Who was the executive vice president of  
2 Ethical Pharmaceuticals in the 1998 to 2002 time  
3 frame?

4 A. Mr. Berkle.

5 Q. And then the third approval is the  
6 president and CEO of BIC. Who was that in the  
7 1998 to 2002 time frame?

8 A. Mr. -- I believe it was Mr. Gerstenberg.

9 Q. And we talked earlier that you weren't a  
10 hundred percent sure what the PTC Committee was;  
11 is that correct?

12 A. Yes.

13 Q. If you look at the bottom where it says  
14 -- bottom of the page we're on in Exhibit 11, it  
15 says -- the very bottom right above the heading  
16 "Review and Approval Process," the sentence above  
17 that says, "Plan changes to prices are extremely  
18 confidential and should be kept to PTC pricing  
19 committee members only."

20 Does that inform your opinion at all as  
21 to the relationship between the PTC Committee and  
22 the pricing committee?

1           A.    My -- looking at this document -- and I  
2   remember your telling me that PTC stands for  
3   pricing terms and conditions and it looks to me  
4   from this document, looking at the third bolded,  
5   underlined point, that here the document refers to  
6   PTC Committee is Pricing Terms and Conditions  
7   Committee.

8                    So I'm not sure if that's what you're  
9   asking or --

10          Q.    Let's switch to Exhibit 12.

11          A.    Okay.

12          Q.    In the approval process here, would you  
13   agree that the recommended prices came from the  
14   pricing committee and they were sent to Shelly  
15   Berkle and Werner Gerstenberg?

16          A.    Yes.

17          Q.    Would you agree that that's consistent  
18   with the approval process that is laid out in the  
19   pricing policy and procedure marked as Exhibit 11?

20          A.    Yes.

21                   MR. FAUCI:  No further questions.

22                   MS. POLLACK:  Can I just confer with